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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/694,108	10/19/2000	Louise Elizabeth Donnelly	7500-0010	7685

23980 7590 10/17/2003

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EXAMINER	
DELACROIX MUIRHEI, CYBILLE	

ART UNIT	PAPER NUMBER
1614	15

DATE MAILED: 10/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/694,108	DONNELLY ET AL.	
	Examiner	Art Unit	
	Cybille Delacroix-Muirheid	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 May 2003 and 05 August 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14,23-33,35,36 and 38-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14,23-33,35,36 and 38-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Detailed Action

The following is responsive to the request for continued examination under 37 CFR 1.114 received Aug. 5, 2003 and the amendment received May 2, 2003.

Claims 15-22, 34 and 37 are cancelled. New claims 38-40 are added. Claims 1-14, 23-33, 35, 36 and 38-40 are currently pending.

The previous claims rejection under 35 USC 102(e) over Fischer et al., 6,329,422 maintained in the office action mailed March 18, 2003 is now **withdrawn** in view of Applicant's amendment and the remarks contained therein.

The previous claims rejections under 35 USC 103(a) set forth in paragraphs 9-11 of the office action mailed July 31, 2002 and in paragraphs 4-6 of the office action mailed March 18, 2003 **are withdrawn** in view of Applicant's amendment and in view of the following new ground(s) of rejection.

Claim Objection(s)

1. Claims 23, 27 and 38 are objected to because of the following informalities: claim 23 is dependent on cancelled claim 22, In claim 27, line 2, the "$\$_2$" should be deleted and replaced with $-\beta_2$--. Finally, in claim 38, line 1, the phrase "pharmaceutical formulation" should be deleted and replaced with –method--. Claim 1 is a method claim. Appropriate correction is required.

Claim Rejections—35 USC 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-14, 23-33, 35, 36 and 38-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. Claims 1, 29 and 31 are vague and indefinite because these claims require the treatment of a patient suffering from both "alveolitis and interstitial lung disease (ILD)". However, Applicant's specification describes alveolitis as a type of ILD not a independent condition distinct from ILD. In fact, dependent claims 38-40 further limit claims 1, 29 and 31 by reciting that the ILD is fibrosing alveolitis. Thus, the scope of the patent protection desired is unclear and one of ordinary skill in the art would not be readily apprised of the scope of the claimed invention.

4. Claim 23 recites the limitation "the organic or inorganic dust" in line 1. There is insufficient antecedent basis for this limitation in the claim. Please note again that claim 22 has been cancelled.

Allowable Subject Matter

Claims 1-14, 23-28 and 38 are free from the prior art because the prior art does not disclose or fairly suggest Applicant's claimed method.

Claim Rejections—35 USC 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 29, 31-33, 39, 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over FISCHER et al., 6,329,422 in view of PEZZUTO et al., 6,414,037 and Goodman & Gilman's Ninth Edition and American Drug Index, Facts and Comparisons (all already of record).

6. FISCHER et al. disclose pharmaceutical compositions for treating cystic fibrosis, chronic bronchitis or asthma, the compositions comprising active agents such as resveratrol and pharmaceutically acceptable aerosol propellants useful for endopulmonary and/or intranasal inhalation administration. The compositions may also

be administered orally. Please see col. 6, lines 58-67; col. 11, lines 47-60; col. 12, lines 61-63; col. 13, lines 24-30; claim 28.

FISCHER et al. do not disclose combining resveratrol with glucocorticoids, NSAID's or antibiotics; however, the Examiner refers to (1) PEZZUTO et al. which disclose pharmaceutical compositions containing resveratrol and anti-inflammatory agents or antibiotics (col. 10, lines 16-19 and lines 45-50) and (2) Goodman & Gilman's which discloses that glucocorticoids are know to be useful in treating asthma (please see page 666).

Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the compositions of FISCHER to additionally include glucocorticoids because such a modification would have been motivated by the reasonable expectation that the combined effect of resveratrol and glucocorticoids would successfully treat the patients suffering from asthma.

Furthermore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the resveratrol containing compositions of FISCHER et al. to include additional anti-inflammatory agents or antibiotics (as suggested by PEZZUTO) because one of ordinary skill in the art would reasonably expect the anti-inflammatory agents or antibiotics to treat or prevent any inflammation or infections that may result from or accompany the asthma, bronchitis or cystic fibrosis. Additionally, it would have been obvious to one of ordinary skill in the art to modify the compositions of FISCHER et al. to additionally administer bronchodilators such as theophylline and salmetrol xinafoate, as taught by American Drug Index, or the use of

antiasthmatics such as cromolyn sulfate and beta-adrenergic agonists, (as taught by Goodman & Gilman's, pages, 666, 667-668), because one of ordinary skill in the art would reasonably expect these bronchodilators and/or the antiasthmatics to be equally effective in treating the patients suffering from asthma. In other words, one of ordinary skill in the art would reasonably expect that the combination of resveratrol and bronchodilators and/or antiasthmatics would successfully treat a subject suffering from asthma.

With respect to claims 39-40 which recite a pharmaceutical formulation for treating ILD such as fibrosing alveolitis, sarcoidiosis or fibrotic lung disease, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). In this case, the Examiner respectfully submits that the pharmaceutical formulations of the prior art of record would be capable of treating the claimed forms of ILD.

7. Claims 30, 35, 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fischer et al. in view of Pezzuto, Goodman & Gilman's and American Drug Index as applied to claims 29, 31-33, 39-40 above, and further in view of Remington's Pharmaceutical Sciences, 15th Edition (already of record).

8. Fischer, Pezzuto, Goodman & Gilman's and American Drug Index as applied above.

However, these references do not disclose that the inhalation compositions are in the form of a dry powder; however the Examiner refers to Remington's Pharmaceutical Science, which discloses that the use of powders as a pharmaceutical dosage form is known and used in aerosols and insufflations (please see page 1554, left hand column, first full paragraph). Remington's also teaches that insufflations are finely divided powders introduced into body cavities such as the nose and throat (please see page 1575, Insufflations). Finally, Remington's discloses that the particles size of the powders may vary (please see page 1554, left hand column, first full paragraph).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the inhalation compositions of Fischer, Pezzuto, Goodman & Gilman's and American Drug Index to be in a dry powder form because, in view of Remington's disclosure, one of ordinary skill in the art would reasonably expect inhalation compositions in dry powder form to effectively deliver the active agent to a patient in need thereof. Furthermore, Remington's discloses that powders possess certain advantages such as stability and rapid therapeutic effect (please see page 1571, second column, Advantages).

In addressing claims 35 and 36, the use of a pharmaceutical sugar as a carrier is obvious and well within the capability of the skilled artisan. As far as claim 36 is concerned, since the efficacy of the formulation is dependent upon particle size of the dry powders, as suggested by Remington's, it would have been obvious to one of ordinary skill in the art to further modify the inhalation compositions such that the particle size of the powders is effective to optimize the compositions therapeutic effect.

Conclusion

Claims 1-14, 23-33, 35, 36 and 38-40 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cybille Delacroix-Muirheid whose telephone number is 703-306-3227. The examiner can normally be reached on Tue-Thur. from 8:30 to 6:00. The examiner can also be reached on alternate Mondays .

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (703) 308-4725 The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

CDM

Oct. 13, 2003

Cybille Delacroix-Muirheid
Patent Examiner Group 1600